DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2002

Mr. Joel Orlinsky
Medical Research Labs, Inc.
1000 Asbury Drive
Buffalo Grove, IL 60089

Re: K012766
Portable Intensive Care Unit (Model PIC2)
Regulation Number: 870.1025
Regulation Name: Arrythmia Detector and Alarm
Regulatory Class: III (three)
Product Code: 74 MKJ, LDD, MWI
Dated: November 16, 2001
Received: November 19, 2001

Dear Mr. Orlinsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

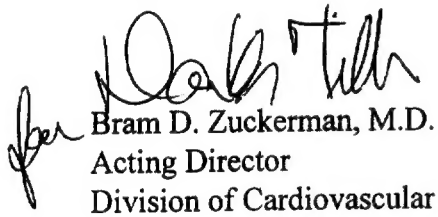
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

JAN 2 3 2002 **Attachment IV**

510(k) Number (if Known): K012766

Device Name: PIC 2

**Indications For Use:**

Without the SAED option, the PIC 2 is intended primarily for use by emergency responders, trained in advanced life support, cardiac care techniques, interpretation of ECG waveforms, and the use of the PIC 2. With the SAED option, the PIC 2 may be used by emergency responders, trained in basic life support, cardiac care techniques, and the use of the PIC 2. The usage may be in an ambulance or at the scene of an emergency. The PIC 2 is also intended for use by (or on the order of) physicians at the scene of an emergency or in a hospital emergency room, intensive care unit, cardiac care unit, or other similar areas of a hospital. It is also intended to be used during the transport of patients between any of the locations mentioned above. The patient population will consist of adults and children (described below), and will consist of patients both with and without heart dysfunction. The PIC 2 will be used primarily on patients experiencing symptoms of cardiac arrest or in a post trauma situation. It may also be used whenever it is required to monitor any of those functions that are included (as options) in the device. Indications for each of the specific functions are discussed below:

**DEFIBRILLATOR FUNCTION:**

The defibrillator function of the PIC 2 is used to treat: ventricular fibrillation and pulseless ventricular tachycardia. The biphasic waveform employed by the PIC 2 has not been clinically tested on pediatric patients The device has not been evaluated for cardioversion of atrial fibrillation or direct (internal) cardiac defibrillation. The semi-automatic mode should not be used on pediatric patients less than 8 years old.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODR)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012766

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109

**ECG MONITOR FUNCTION:**
The ECG monitor function of the PIC 2 is used to monitor and/or record ECG waveform and heart rate, and to alarm when heart rate is above or below limits set by the operator. The PIC 2 also provides output signals for the purpose of sending ECG waveforms to a remote monitor via direct connection, telephone, or radio transmission. Patients may range from neo-natal to adult.

**EXTERNAL TRANSCUTANEOUS PACEMAKER FUNCTION:**
The external transcutaneous pacing function of the PIC 2 is used for the emergency treatment of hemodynamically compromising bradycardia, bradycardia with escape rhythms that are unresponsive to pharmacologic therapy, refractory tachycardia (supraventricular or ventricular), and bradyasystolic cardiac arrest. Patients may range from pediatric to adult.

**NON-INVASIVE BLOOD PRESSURE FUNCTION:**
The non-invasive blood pressure function of the PIC 2 is used to make non-invasive measurements of arterial pressure and heart rate, and to alarm if either parameter is outside of the limits set by the user. Measurements are made using an inflatable cuff on the patient's arm or (occasionally) leg. Patients may range from pediatric to adult.

**TEMPERATURE MONITOR FUNCTION:**
The temperature monitor function of the PIC 2 is used to make continuous measurements of rectal, esophageal, or surface temperature, and to alarm if the temperature is outside of the limits set by the user. It is used on patients ranging from neo-natal to adult.

**PULSE OXIMETER FUNCTION:**
The pulse oximeter function of the PIC 2 is used to monitor pulse rate and oxygen saturation of arteriolar hemoglobin, and to alarm if either parameter is outside of the limits set by the user. It is used on patients ranging from neo-natal to adult. Measurements are made non-invasively at remote sites such as a finger, toe, ear lobe, bridge of nose, etc. It is used on patients ranging from neo-natal to adult.

**RESPIRATION RATE MONITOR FUNCTION:**
The respiration rate monitor function of the PIC 2 is used to continuously monitor respiration rate and to alarm if the rate falls outside of the range set by the operator. The patients range from neo-natal to adult. Because the measurement method actuall measures respiratory effort, apnea episodes with continued respiratory effort (such as obstructive apnea) may not be detected. It <u>is not intended</u> to be used as an apnea monitor. It is used on patients ranging from neo-natal to adult.

## $CO_2$ MONITOR FUNCTION

The respiration rate monitor function of the PIC 2 is used to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory status. This device is intended as an indicator of patient carbon dioxide concentration during expiration and is not intended as the sole basis for medical diagnosis.

This $CO_2$ monitor is intended for use with patients 3 years of age and older. This device is not recommended for patients with low tidal volume such as patients younger than 3 years of age or weighing less than 22 pounds, or patients with a respiration rate greater than or equal to 60 breaths per minute.